

Material safety data sheet SDS

According to EU Regulation 1907/2006 in the current version

Noni Biomics

1. Identification of the substance/mixture and company

Product name: Noni Biomics
INCI: Glycerin, Morinda Citrifolia Fruit Extract, Citric Acid
Uses: Cosmetic ingredient
Supplier company identification: Elemental SRL, Piața Cazărmii no.15, 410188-Oradea, jud.Bihor, Romania
Tel/Fax: +40259-436.755, www.elemental.com
Emergency: RO: număr național pentru cazuri de urgență: 021 3183606 Institutul de Sănătate Publică București.
International emergency number: +49 180 2273-112

2. Hazards Identification

2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [CLP]

2.2. Label elements

This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [CLP]

Hazard statements

This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [CLP]

2.3. Other hazards

No information available.

3. Declaration of ingredients

3.1 Substances

n/a

3.2 Mixtures

INCI % CAS No EC No

Glycerin 68.00 - 69.00 56-81-5 200-289-5

Morinda Citrifolia Fruit Extract 29.00 - 31.00 84929-68-0 284-551-4

Citric Acid 1.00 - 2.00 5949-29-1 201-069-1

The product contains no substances which at their given concentration, are considered to be hazardous to health

Full text of H- and EUH-phrases: see section 16

This product does not contain candidate substances of very high concern at a concentration $\geq 0.1\%$ (Regulation (EC) No. 1907/2006 (REACH), Article 59)

4. First aid measures

4.1. Description of first aid measures

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Inhalation Remove to fresh air. Get medical attention immediately if symptoms occur.

Eye contact Rinse thoroughly with plenty of water, also under the eyelids. If eye irritation persists: Get medical advice/attention.

Skin contact No hazards which require special first aid measures.

Ingestion Clean mouth with water. Drink 1 or 2 glasses of water. Get medical attention if symptoms occur.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms No information available.

4.3. Indication of any immediate medical attention and special treatment needed

Note to doctors Treat symptomatically.

5. Fire fighting measures

5.1. Extinguishing media

Suitable Extinguishing Media Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Small Fire Dry chemical, CO2 or water spray.

Large Fire Alcohol resistant foam. Water spray.

Unsuitable extinguishing media Full water jet.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical

No information available.

5.3. Advice for firefighters

Special protective equipment and precautions for fire-fighters

Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Use personal protective equipment as required.

Other information Refer to protective measures listed in Sections 7 and 8.

For emergency responders Use personal protection recommended in Section 8.

6.2. Environmental precautions

Environmental precautions Prevent further leakage or spillage if safe to do so. Do not flush into surface water or sanitary sewer system. See Section 12 for additional Ecological Information.

6.3. Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Take up mechanically, placing in appropriate containers for disposal.

Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

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Reference to other sections See section 7 for more information. See section 8 for more information. See section 13 for more information.

7. Handling and storage

7.1. Precautions for safe handling

Advice on safe handling Ensure adequate ventilation.

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Keep in a dry place. Protect from light. Keep at a temperature not exceeding 20 °C.

7.3. Specific end use(s)

Risk Management Methods (RMM) The information required is contained in this Material Safety Data Sheet.

8. Exposure controls / personal protection

8.1. Control parameters

Exposure Limits This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

Biological occupational exposure limits

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies.

Derived No Effect Level (DNEL) No information available.

Predicted No Effect Concentration (PNEC) No information available.

8.2. Exposure controls

Personal protective equipment

Eye/face protection Goggles.

Hand protection Wear suitable gloves

Skin and body protection Wear suitable protective clothing. Respiratory protection No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required. General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

Environmental exposure controls No information available.

9. Physical and chemical properties

9.1 Information on basic physical and chemical properties:

Appearance

Physical state Liquid

Colour yellowish

Odour characteristic

Melting point / freezing point No data available

Boiling point / boiling range No data available

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Flammability (solid, gas) No data available
Flammability Limit in Air
Upper flammability or explosive limits
No data available
Lower flammability or explosive limits
No data available
Flash point No data available
Autoignition temperature No information available Product is not self-igniting.
Decomposition temperature No data available
pH 2.0-3.5
pH (as aqueous solution) No data available
Kinematic viscosity No data available
Dynamic viscosity No data available
Water solubility Immiscible in water
Solubility(ies) dispersible in water and ethanol
Partition coefficient No data available
Vapour pressure No data available
Relative density 1.10-1.30 g/ml
Bulk density No data available
Vapour density No data available
Particle characteristics
Particle Size No information available
Particle Size Distribution No information available
Surface tension No data available

9.2 Other information: No additional information available.

10. Stability and reactivity

10.1. Reactivity
Reactivity No information available.
10.2. Chemical stability
Stability Stable under normal conditions.
Explosion data
Sensitivity to mechanical None.
Sensitivity to static discharge None.
10.3. Possibility of hazardous reactions
Possibility of hazardous reactions No known hazardous reactions.
10.4. Conditions to avoid
Conditions to avoid None known based on information supplied.
10.5. Incompatible materials
Incompatible materials None known based on information supplied.

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10.6. Hazardous decomposition products

Hazardous decomposition products

None known based on information supplied

11. Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

In vivo TESTING

Skin tolerance

Assessment of the skin local tolerance of the studied product after an epicutaneous test performed in occluded conditions, during 48 hours on a panel of 12 healthy adult volunteers: Patch test method.

According to the experimental conditions of the study, the product QUORA NONI-C 02 can be considered as NON-IRRITANT regarding its primary skin tolerance.

Skin sensitization (Hypoallergenicity)

Assessment of the irritating and sensitizing potential in vivo of the product QUORA NONI-C 02 through an HRIPT (Human Repeated Insult Patch Test) performed according to the Marzulli-Maibach method. The HRIPT was performed during 6 weeks on a panel of 56 healthy adult volunteers.

According to the experimental conditions of the study, the product did not cause sensitization in any volunteer so it can be considered NON-IRRITATING, NON-SENSITIZING and HYPOALLERGENIC.

In vitro TESTING

Cytotoxicity on Human Monocytes (THP-1)

No signs of cytotoxicity were observed at the tested concentrations.

Cytotoxicity on Human Epidermal Keratinocytes (HEK)

No signs of cytotoxicity were observed at the tested concentrations.

Evaluation of skin irritation

Assessment of the skin irritation potential of the product QUORA NONI-C 02 using Reconstructed Human Epidermis (RHE) and the validated Method OECD 439 (In Vitro EpiDerm™ Skin Irritation Test).

According to the experimental conditions of the study, the product QUORA NONI-C 02 is considered NON-IRRITANT for the skin.

Evaluation of ocular irritation

Assessment of the ocular irritation potential of the product QUORA NONI-C 02 using the Neutral Red Release (NRR) assay, with rabbit cornea fibroblasts (SIRC cells). This method is registered in the Official Journal of French Republic (JORF - Decree of 27 December 1999).

In the performed experimental conditions, the product QUORA NONI-C 02, tested by NRR method at 3.30% concentration and according to the JORF classification, presents a NEGLIGIBLE CYTOTOXICITY.

Mutagenicity test

Assessment of mutagenic potential according to OECD 471 Bacterial reversion mutation test (Ames test). The product was assayed at 5 concentrations ranging from 50 - 5.000 µg/plate.

In the performed experimental conditions, the product QUORA NONI-C 02 is considered NON MUTAGENIC nor PRO-MUTAGENIC.

11.2. Information on other hazards

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Endocrine disrupting properties No information available.
Other adverse effects No information available

12. Ecological information

12.1. Toxicity

No information available.

12.2. Persistence and degradability

The product is biodegradable at 78% after 28 days of test (According to OECD 301 F Guideline).

12.3. Bioaccumulative potential

Bioaccumulation No information available.

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment No information available.

12.6. Other adverse effects

Endocrine disrupting properties No information available.

12.7. Other adverse effects

No information available.

13. Disposal considerations

13.1. Waste treatment methods

Waste from residues/unused products

Should not be released into the environment. Dispose of waste in accordance with environmental legislation. Dispose of in accordance with local regulations.

Contaminated packaging Packaging may be reused or recycled after cleaning.

14. Transport information

Land transport (ADR/RID)

14.1. UN number: No dangerous good in sense of this transport regulation.

14.2. UN proper shipping name: No dangerous good in sense of this transport regulation.

14.3. Transport hazard class(es): No dangerous good in sense of this transport regulation.

14.4. Packing group: No dangerous good in sense of this transport regulation.

Inland waterways transport (ADN)

14.1. UN number: No dangerous good in sense of this transport regulation.

14.2. UN proper shipping name: No dangerous good in sense of this transport regulation.

14.3. Transport hazard class(es): No dangerous good in sense of this transport regulation.

14.4. Packing group: No dangerous good in sense of this transport regulation.

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Marine transport (IMDG)

- 14.1. UN number: No dangerous good in sense of this transport regulation.
- 14.2. UN proper shipping name: No dangerous good in sense of this transport regulation.
- 14.3. Transport hazard class(es): No dangerous good in sense of this transport regulation.
- 14.4. Packing group: No dangerous good in sense of this transport regulation.

Air transport (ICAO-TI/IATA-DGR)

- 14.1. UN number: No dangerous good in sense of this transport regulation.
- 14.2. UN proper shipping name: No dangerous good in sense of this transport regulation.
- 14.3. Transport hazard class(es): No dangerous good in sense of this transport regulation.
- 14.4. Packing group: No dangerous good in sense of this transport regulation.
- 14.5. Environmental hazards: No
- 14.6. Special precautions for user: No dangerous good in sense of this transport regulation.
- 14.7. Maritime transport in bulk according to IMO instruments: No dangerous good in sense of this transport regulation.

15. Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

REACH Registration, Evaluation, Authorisation and Restriction of Chemicals (Regulation (EC) No 1907/2006)

We hereby confirm that each single ingredient of our PRODUCT manufactured in and/or imported into the European Community is taken into account in fulfilment of the requirements given by the REACH Regulation (EC) No 1907/2006.

We hereby confirm that the product does not contain substances listed in the current Candidate List of substances of very high concern (SVHC) at concentrations of 0.1 % w/w or higher. Furthermore, the product does not contain substances listed in REACH Annex XIV (Authorisation List) nor in REACH Annex XVII (Restricted Substances List) at concentrations of 0.1 % w/w or higher.

The product is compliant with the following rules and regulations:

European Union Cosmetic Regulation (EC) No 1223/2009: Annex II – substances which should not be used in cosmetics Annex III – restricted substances Annex IV – colouring agents Annex VI – UV-filters U.S.A. 21 CFR Food and Drugs.

Provisions § 700.11 to § 700.16 California Proposition 65 Japan Standard for Cosmetics in accordance to Pharmaceutical Affairs Law (Law No 145 of 1960) Appendix 1. Prohibited materials Appendix 2, 3 and 4. Restricted ingredients Canada None of the ingredients contained in this product is included in the Cosmetic Ingredient Hotlist (2015) of prohibited and restricted ingredients for use in Cosmetic Products.

NAGOYA PROTOCOL Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity Exempt CITES Convention on International Trade in Endangered Species of Wild Fauna and Flora Not listed

15.2. Chemical safety assessment

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Chemical Safety Report No information available

16. Additional information

16.1 Abbreviations

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Test-ing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regula-tion (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergen-cy Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration as-sociated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good La-boratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships car-rying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - Interna-tional Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; INCI: International Nomenclature of Cosmetic Ingredients; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test popula-tion; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - Interna-tional Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Ef-fect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic sub-stance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quanti-tative) Structure Activity Relationship; PNEC: Predicted No Effect Concentration; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Re-striction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; STE: Short-term exposure; STEL: Short Term Exposure limit; STOT: Specific Target Organ Toxicity; TCSI - Taiwan Chemical Substance Inventory; TECl - Thailand Existing Chemicals Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Disclaimer:

This material safety data sheet does not constitute a guarantee of the properties of the product and is not a contractual legal report. The information is given in good faith on the basis of our best knowledge of the product at the indicated time. However, we cannot accept responsibility or liability for any consequences arising from its use, no warranty for correctness and completeness is given. We caution the users against the incurred possible risks when the product is used at other ends than the use for which it was initially planned. It is the user's responsibility during handling, storage and product use to consult the main regulatory texts in force regarding workers and environment protection.